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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; and THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

vs.

JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL

Defendants.

Civil Action No. 19-12107 (KM) (ESK)

MEMORANDUM IN SUPPORT OF DEFENDANTS' JOINT MOTION TO DISMISS SECOND AMENDED COMPLAINT

Motion Date: Apr. 6, 2021

Document electronically filed

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Regulations

Other Authorities

INTRODUCTION

Zachary Silbersher is a patent attorney whose practice includes "investigating invalid pharmaceutical patents" and challenging them through *inter partes* review ("IPR") proceedings. Second Amended Complaint ("SAC"), ECF 63 ¶16.[1] More recently, Mr. Silbersher has pivoted from counsel to litigant,[2] filing False Claims Act ("FCA") suits premised on alleged inequitable conduct—a breach of the duty of candor owed to the U.S. Patent and Trademark Office ("PTO").[3] In these suits, he asserts that Defendants fraudulently secured or defended patents and then—years later—violated the FCA by submitting claims for reimbursement that were "false" inasmuch as the drugs' prices were higher than they would have been if subject to generic competition**.**

Relator's novel claims fail for three reasons. *First*, Relator relies exclusively on information previously disclosed by others. Unlike the usual *qui tam* plaintiff—an employee, contractor, or suchlike exposing hidden misconduct—Relator has no relationship with Defendants. Instead, the SAC repackages materials previously disclosed in patent-related proceedings. The FCA's public disclosure bar prohibits such claims. *Second*, Relator's twice-amended complaint fails to plead essential elements of the FCA: an actionable false claim material to payment. *Third*, Relator fails to plead the scienter and materiality required for a claim predicated on inequitable conduct.

This Court should dismiss the SAC as to Defendant BTG International ("BTG") for two

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[1] *See* Kroub, Silbersher & Kolmykov PLLC, *Zachary Silbersher*, http://www.kskiplaw.com/silbersher.html (last visited Apr. 5, 2021).

[2] Precisely how Mr. Silbersher went about doing this, and his relationship with his former clients, has sparked some controversy. *See* Brief of Amicus Curiae Flat Line Capital LLC, *Silbersher v. Valeant Pharm., Inc.*, No. 20-16176 (9th Cir. Mar. 22, 2021), Dkt. No. 66, (alleging Mr. Silbersher's complaint relied on information divulged by amicus for the purpose of litigation).

[3] In Relator's other two lawsuits, the defendants also filed motions to dismiss. One motion was granted, and the case was dismissed with prejudice. *See Silbersher v. Valeant Pharm. Int'l, Inc.*, No. 445 F. Supp. 3d 393 (N.D. Cal. 2020). The other motion was denied, but the court granted the defendants' request to seek interlocutory review. *See Silbersher v. Allergan Inc.*, No. 18-cv-03018-JCS, 2020 WL 7319407 (N.D. Cal. Dec. 11, 2020). Both cases are presently on appeal to the Ninth Circuit. *See* No. 20-16176 (9th Cir. June 16, 2020); No. 21-15420 (9th Cir. Mar. 10, 2021).

additional reasons: *First*, the SAC does not allege that BTG participated in the alleged fraud or even knew about it. *Second*, the SAC does not allege any facts that show BTG presented any false claims or caused any false statements or claim to be made to any government agency. The SAC thus fails to put BTG on notice of any conduct it engaged in that would satisfy the FCA's proximate-cause standard.

BACKGROUND

Defendant BTG developed and licenses, and the J&J Defendants[4] market and sell, the drug abiraterone acetate ("abiraterone") under the brand name Zytiga. SAC ¶5. Zytiga is indicated for use with prednisone, an anti-inflammatory steroid, to extend the lives of patients with metastatic castration-resistant prostate cancer ("mCRPC")—an advanced, deadly form of prostate cancer resistant to first-line treatments. *See id.* ¶¶5, 59. In 2011, the U.S. Food & Drug Administration ("FDA") approved Zytiga for use with prednisone by chemo-refractory patients (*i.e.*, post-chemotherapy). In 2012, FDA approved it for chemo-naïve patients (*i.e.*, no prior chemotherapy) under the Priority Review Program. *See, e.g.*, Request for Judicial Notice ("RJN"), Ex. C at 45 of 384 (PDF page).[5]

Relator alleges Defendants violated the FCA by presenting false claims for payment for Zytiga to various federal and state programs since December 2016. SAC ¶¶107–119. Relator does not assert Defendants factually misrepresented the product sold, the quantity, or its contractual price. Rather, Relator contends that Zytiga's entire market was corrupted, rendering the price the Federal Government itself determined using its own pricing formula "false."

Before drug sales may be reimbursed through various federal programs, a vendor must first

[4] As it is not germane to this Motion, Defendants do not parse which J&J entity did what.
[5] The RJN includes publicly disclosed information relied upon by the SAC. Defendants cite these articles to show that Relator's case is built entirely on public information, but their inclusion does not indicate that Defendants necessarily accept or concede any statements made therein.

enter into a Master Agreement and a Pharmaceutical Price Agreement ("PPA"). *Id.* ¶112. The PPA provides the Government with the Average Manufacturer Price ("AMP") paid by commercial customers. *Id.* Federal law sets a Federal Ceiling Price ("FCP") that limits the price paid by the Government for any pharmaceutical to no more than 76% of the AMP. *Id.*

To qualify for reimbursement, a product must appear on the Federal Supply Schedule ("FSS"), *id.*, which lists prices the Government pays for various products. To list a product on the FSS, an applicant must provide pricing information for both their "Most Favored Customer"—*i.e.*, the lowest-paying customer—and a "Tracking Customer"—*i.e.*, a customer whose price is tracked against the awarded FSS price for the life of the contract. *Id.* ¶¶112–116. The General Services Administration ("GSA") issues a document (the "Solicitation") that explains the structured review procedures for Federal contracting officers to determine if the offered prices are "fair and reasonable." *Id.* ¶¶113–114.[6] The Solicitation requires applicants to submit accurate pricing data, and its terms permit the Government to cancel a contract if inaccurate information is provided. *Id.* ¶114.

Relator does not allege that Defendants submitted incorrect pricing data. Nor does Relator suggest that the statutory pricing formula was misapplied. Rather, Relator alleges that the calculation was based on an improperly inflated commercial price for Zytiga that was *per se* unfair and unreasonable. *Id.* ¶117. Defendants, Relator alleges, fraudulently procured a patent for mCRPC treatments using abiraterone and prednisone and then excluded competing generic treatments by filing subsequent sham lawsuits under the Hatch-Waxman Act. *Id.* ¶105.

Two U.S. patents have covered Zytiga: No. 5,604,213 ("the '213 Patent"), *see* RJN, Ex. A, which expired in December 2016; and No. 8,822,438 ("the '438 Patent"), *see* RJN, Ex. B, granted

[6] For pharmaceutical products, the GSA has delegated its authority to the Department of Veterans Affairs ("VA"). 48 C.F.R. §8.402(a).

in 2014. *See* SAC ¶¶92–93. Once issued, Defendants listed the '438 Patent in the FDA's Orange Book. *Id.* ¶92. Thereafter, several generic manufacturers filed abbreviated new drug applications ("ANDAs") containing Paragraph IV certifications. *Id.* ¶94.[7] Defendants then filed infringement suits in this District, triggering the Hatch-Waxman Act's temporary stay on all FDA approvals of generic abiraterone. 21 U.S.C. §355(c)(3)(C); *see also* SAC ¶¶51, 99.

Relator contends these suits were a "sham," filed not to enforce the '438 Patent, but to exclude generic competition. SAC ¶105. That is, the lawsuits were "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60, 65 (1993), a standard akin to Rule 11 frivolousness. According to Relator, the Hatch-Waxman stay allowed Defendants to continue to charge higher prices for Zytiga. SAC ¶¶99, 108.

But none of *these* events forms the basis for Relator's allegations of fraud. For that, Relator reaches further back in time to a different proceeding before a different agency—the PTO.

When first approved by the FDA in 2011, Zytiga was covered by the '213 Patent, which claimed the compound abiraterone acetate. *See* RJN, Ex. A. In 2011, J&J filed patent application 13/034,340 ("the '340 Application") for a method of administering therapeutically effective amounts of abiraterone acetate in combination with prednisone to treat prostate cancer. SAC ¶68. The PTO initially denied the Application for obviousness, before concluding in 2014 that secondary considerations—such as commercial success—supported a grant. *Id.* ¶¶25, 75–76, 85. Relator alleges that Defendants fraudulently induced the '438 Patent by making "false and misleading representations" to the PTO. *See id.* ¶90.

[7] ANDAs are applications to market a generic product. An ANDA applicant may indicate whether the proposed drug implicates a patent listed in the Orange Book, and, if so, must certify that the patent is either not infringed by the proposed drug or is invalid (a "Paragraph IV certification"). *See* 21 C.F.R. §314.94(a)(12)(i)(A)(4); SAC ¶48(d).

The FCA prohibits presenting false claims for payment, and false statements material to (*i.e.*, that might influence) such claims. Yet Relator's allegations of misrepresentations before the PTO, unrelated to any presentment of any claim for payment from the Government—are far removed in time and target from any cognizable claim. By Relator's telling: Defendants defrauded the PTO into issuing a patent; which Defendants listed in the Orange Book; which generic manufacturers attacked in Paragraph IV certifications; which Defendants challenged in infringement actions; which triggered a stay of approval; which temporarily prevented generics from entering the market; which allowed Defendants to charge higher prices for Zytiga; which elevated the market prices submitted to Federal officials; which led Government officials to accept a price for Zytiga that was too high; which made Zytiga's federal list price not "fair and reasonable"; which made claims for reimbursement at that price false. This daisy-chain theory fails for multiple reasons.

Relator was not the first (nor even the second or third) to challenge the '438 Patent and dispute Zytiga's commercial success. In Defendants' infringement actions, filed in this Court in July 2015, various generic companies contested the validity of the '438 Patent. Generic manufacturers also challenged Zytiga's patentability in five IPR[8] petitions. Two years into the publicly litigated IPRs, and only after dispositive briefing closed, Relator filed this action under seal, parroting those IPR pleadings. *Id.* ¶¶63–91; *see also infra* Section A.1.

In January 2018, within a month of Relator filing this action, and after weighing a contentiously developed record, the Patent Trial and Appeal Board ("PTAB") issued final decisions deeming the '438 Patent claims unpatentable. Meanwhile, the United States investigated Relator's claims, declining to intervene in September 2018, with the Plaintiff States following suit.

[8] An IPR is a statutory procedure by which a third party may request cancellation of a patent claim because it does not meet the standards for patentability. *See* 35 U.S.C. §§311–319.

Concurrently, after a bench trial this Court issued its decision in the infringement action. *See BTG Int'l Ltd. v. Amneal Pharm. LLC*, 352 F. Supp. 3d 352 (D.N.J. 2018). The Court recognized that Zytiga had "enjoyed commercial success," and "there [was] evidence supporting the unmet-need or failure-of-other factors," even if not "powerful." *Id.* at 387–89.[9] On balance, however, the Court concluded this evidence was insufficient to overcome obviousness.

Throughout the various challenges to the '438 Patent, after the Federal and state governments declined to intervene, and to this day, the Federal and various state governments have continued to pay for Zytiga. *See, e.g.*, SAC ¶144.

LEGAL STANDARDS

A complaint must be dismissed if it does not "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[L]abels and conclusions," "formulaic recitation[s] of the elements of a cause of action," and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements" are insufficient. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555). Because FCA claims sound in fraud, they must be pled with Rule 9(b) particularity. *See, e.g.*, *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156–57 (3d Cir. 2014). In reviewing its sufficiency, courts may consider the contents of the complaint, documents incorporated by reference, and other matters subject to judicial notice. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322–23 (2007). Courts accept a complaint's well-pled facts as true, but disregard legal conclusions, including those couched as factual allegations. *See In re Plavix Mktg., Sales Practices & Prods. Liab. Litig.*, 123 F. Supp. 3d 584, 593 (D.N.J. 2015) (*Plavix I*). If a third

[9] The Federal Circuit affirmed the PTAB's order regarding the '438 Patent's claims, and dismissed an appeal from this Court's order as moot. *See BTG Int'l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063 (Fed. Cir. 2019). No court has suggested that Defendants obtained the '438 Patent through any sort of fraudulent conduct or that the lawsuits were frivolous.

amended complaint would be futile or demonstrate undue delay, dismissal with prejudice is appropriate, particularly when, as here, Relator "was put on notice as to the deficiencies in his complaint, but chose not to resolve them." *U.S. ex rel. Schumann v. Astrazeneca Pharm. L.P.*, 769 F.3d 837, 849 (3d Cir. 2014).

ARGUMENT

I. RELATOR'S CLAIMS ARE PRECLUDED BY THE PUBLIC DISCLOSURE BAR

The FCA bars claims premised on facts that are "substantially the same" as prior publicly disclosed information unless the relator qualifies as an "original source." 31 U.S.C. §3730(e)(4); *see U.S. ex rel. Moore & Co. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 297 (3d Cir. 2016). "A disclosure is 'sufficiently public' if the information therein 'would have been equally available to strangers to the fraud transaction had they chosen to look for it as it was to the relator.'" *Plavix I*, 123 F. Supp. 3d at 596. The public disclosure bar "strike[s] a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." *Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 295 (2010). Not all public disclosures trigger the bar. Rather, a disclosure must have been made through a statutorily-enumerated channel. *See* 31 U.S.C. §3730(e)(4)(A). Relator's claims fall squarely within the public disclosure bar: they are based exclusively on information made public through the statutory channels, and Relator does not separately qualify as an original source.

A. Relator's Claims Rely On Publicly Disclosed Information.

The public disclosure bar applies when "substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" in an enumerated channel of disclosure. *See id.* As used in the statute, "allegation" refers to a "specific allegation of wrongdoing," whereas a "transaction" "raises an inference of fraud consist[ing] of both the allegedly misrepresented facts and the allegedly true state of affairs." *United States v. Omnicare, Inc.*, 903 F.3d 78, 83 (3d Cir.

2018). An allegation or transaction is "substantially the same" if it is "based upon" the public disclosures. *Id.* at 84 n.6; *see also U.S. ex rel. Judd v. Quest Diagnostics, Inc.*, No. CIV. 10-4914 KM, 2014 WL 2435659, at *5 n.5 (D.N.J May 14, 2014), *aff'd*, 638 F. App'x 162 (3d Cir. 2015). Both Relator's allegations and the underlying transactions were publicly disclosed before Relator filed this lawsuit.[10]

1. Relator's Core Allegations Were Publicly Disclosed.

The SAC pleads a paradigmatic "parasitic lawsuit[]." *U.S. ex rel. Zizic v. Q2Administrators, LLC*, 728 F.3d 228, 235 (3d Cir. 2013). Drawn from patent filings, pleadings, petitions, and media searches, the SAC merely repackages publicly available information. At core, the SAC pleads that Defendants misled the PTO that the invention claimed by the '340 Application (*i.e.*, the co-administration of therapeutically effective amounts of abiraterone with therapeutically effective amounts of prednisone) had enjoyed commercial success by (1) misrepresenting Zytiga's market share as a measure of commercial success, and/or (2) omitting information suggesting Zytiga's commercial success was not attributable to the claimed invention. *See* SAC ¶¶82–90.[11] But these same allegations had already been made in the IPR petitions, which also alleged that J&J mischaracterized the scale and source of Zytiga's commercial success.

The IPR petitions were all publicly available on the PTAB website at or near the time of their filing between December 2015 and February 2017—well before Relator's December 2017

[10] Appendix A is a chart comparing Relator's allegations with relevant public disclosures. For the Court's convenience, Defendants have also submitted under separate cover a hyperlinked version of Appendix A that includes a copy of the SAC, with relevant paragraphs highlighted, and true and correct copies of Exhibits A through RR to Defendants' RJN.

[11] Although Relator ultimately argues (albeit without particularity) that Defendants made false claims to the Government that the price of Zytiga was fair and reasonable, SAC ¶¶113–118, the daisy-chain nature of his theory requires him to show that Defendants' statements to the PTO had not been previously publicly disclosed. Still, Zytiga's FSS information was publicly available through the VA's website, thereby revealing that the Government deemed Zytiga's price "fair and reasonable." Zytiga was available through an FSS contract beginning in 2011 and its price would have been publicly available through the FSS website in 2017. *See* RJN, Exs. GG, HH.

sealed filing. *See* Amerigen Pet., RJN, Ex. D; Mylan Pet., RJN, Ex. E; Wockhardt Pet., RJN, Ex. F. The SAC's material claims were publicly disclosed in the IPR petitions:

First, Relator attacks J&J's prosecution arguments that Zytiga enjoyed commercial success attributable to the claimed invention. For example, Relator asserts: (i) any new anti-cancer drug will have some commercial success due to the drug-resistant nature of mCRPC, SAC ¶87(b); (ii) "Zytiga was recommended in some cases because it was the least toxic" of available therapies, *id.* ¶87(d); and (iii) doctors and patients may have chosen Zytiga for reasons other than the alleviation of certain side effects, *i.e.* because Zytiga was effective at treating mCRPC, *id.* ¶87(f).

This rehashes the IPRs, which similarly asserted that Defendants failed to show a nexus between Zytiga's commercial success and the claimed invention. *Compare* Amerigen Pet., RJN, Ex. D at 48–52 (J&J "presented *no* evidence to suggest that the claimed invention, rather than the prior art abiraterone acetate, was responsible for any commercial success of Zytiga.®") (emphasis added); Mylan Pet., RJN, Ex. E at 51–54 ("any commercial success of Zytiga® has not been shown to derive from the claimed invention, *i.e.*, the combination of abiraterone acetate and prednisone"); Wockhardt Pet., RJN, Ex. F at 60–62 (J&J "failed to provide any evidence [of a] nexus between the Zytiga® sales and the '438 patent"), *with* SAC ¶87(b)–(g), (i) (alleging facts, not disclosed to the PTO, that purportedly demonstrate Zytiga's commercial success lacked nexus to the claimed invention and was attributable to other factors). The IPRs even discussed "the safety and tolerability" of the co-administration of prednisone because it "reduc[ed] the potential for side effects." Amerigen Pet., RJN, Ex. D at 27, Mylan Pet., RJN, Ex. E at 28; *see also* Wockhardt Pet., RJN, Ex. F at 31.

Second, Relator's claims that Defendants mischaracterized the mCRPC therapy market and the success of competing products, SAC ¶84, also come from the IPRs. For instance, Wockhardt

attacked J&J's statement that Zytiga maintained commercial success after the introduction of competitor Xtandi because Xtandi subsequently overtook Zytiga's market share. Relator cites that same Zytiga-to-Xtandi market shift. *Compare* Wockhardt Pet., RJN, Ex. F at 62–63, *with* SAC ¶84(a). The media also reported on Xtandi's surpassing of Zytiga. *See, e.g.*, RJN, Ex. R at 2.

Third, like the IPR petitioners, Relator questions how J&J defined the relevant market for measuring commercial success, even citing the same business presentation slide J&J had submitted to the PTO. Relator argues the slide's market-share comparison is fraudulent because it compared Zytiga and Xtandi in a submarket for which Xtandi had not yet received FDA approval. *See* SAC ¶84(d); RJN, Ex. C at 58 of 384 (PDF page) (June 4, 2013 submission). The IPR petitions similarly attacked the slide's presentation of Zytiga's market share "in the 'post-chemo' mCRPC market prior to the launch of Xtandi" as "misleading and incomplete … because Zytiga was not an unexpected commercial success when viewed in the proper market context." *See* Mylan Pet., RJN, Ex. E at 52–53; Amerigen Pet., RJN, Ex. D at 49–50.

Lastly, Relator repeats the IPR petitions' argument that the '213 Patent "blocked" the commercial development of abiraterone, thus "cast[ing] substantial doubt" on Zytiga's sales success. *Compare* SAC ¶87(e), *with* Amerigen Pet., RJN, Ex. D at 57–59; Mylan Pet., RJN, Ex. E at 59–61; Wockhardt Pet., RJN, Ex. F at 56–59. Relator even repeats the canard that this "blocking patent" was not disclosed to the PTO. *Compare* SAC ¶87(e), *with* Amerigen Pet., RJN, Ex. D at 34; Mylan Pet., RJN, Ex. E at 35. The allegation is both derivative and false. The '213 Patent was disclosed publicly, including to the PTO, through the '340 Application's specification. *See* RJN, Ex. I at 7, 10 ('340 Application specification). Medical journals also reported that the exclusivity enjoyed by Zytiga due to the existing '213 composition patent would be extended as a result of the

newly granted '438 method-of-use patent.[12]

Relator's *allegations* regarding Defendants' conduct before the PTO are thus "substantially the same" as claims made in the IPR petitions. *Moore*, 812 F.3d at 301.

2. The Transactions Underlying Relator's Allegations Were Publicly Disclosed.

The *transactions* constituting Relator's claims were also publicly disclosed, both in the patent prosecution and through the media. *See* 31 U.S.C. §3730(e)(4). Whether a transaction giving rise to "an inference of fraud [] has been publicly disclosed such that the public disclosure bar is triggered," is governed by "a formula … X + Y = Z," where "Z represents the allegation of fraud and X and Y represent its essential elements," *i.e.*, the misrepresented facts and the true state of affairs. *Omnicare*, 903 F.3d at 83–84. Here, the "X"—allegedly misleading statements or omissions in the June 4 submission—were publicly disclosed to the PTO during the patent prosecution. *Compare* SAC ¶¶82–84, 87, *with* Ex. C at 36–38 of 384 (PDF page). And the "Y"—information Relator claims *should* have been disclosed to the PTO—can be grouped into three categories and was either included in that same June 4 submission to the PTO or publicly disclosed through other media sources:

First, Relator alleges Defendants misled the PTO by: (1) comparing Zytiga's market share in the chemo-naïve submarket to Xtandi, which was not yet FDA-approved for that use, SAC ¶84(a)–(d); (2) withholding the dates of Xtandi's FDA approvals, *id.* ¶84(d); and (3) submitting market-share data based on patient-share rather than direct sales, "because patients suffering from prostate cancer often take many drugs," *id.* ¶84(e).

But this was all publicly disclosed to the PTO through J&J's June 4 submission. That submission included an FDA press release announcing Xtandi's FDA approval date for the *chemo-*

[12] *See, e.g.*, RJN, Ex. S at S492–93 (discussing how the '438 Patent will "extend the period of exclusivity" beyond the preexisting '213 Patent).

refractory market only, and the purportedly misleading slide referenced in the SAC expressly distinguished the two submarkets (chemo-refractory and chemo-naïve) in which the products were being compared. J&J obviously could not have disclosed Xtandi's not-yet-extant approval date for the chemo-naïve market, and Relator pleads no plausible basis to assume a sophisticated PTO examiner would conclude that a press release indicating FDA approval in one submarket indicated FDA approval in the other. *Id.* ¶84(a). Moreover, Xtandi's FDA approval for chemo-refractory patients and subsequent September 2014 approval for chemo-naïve patients—*after* the issuance of the '438 Patent—were reported in the press,[13] and FDA's website specifies Xtandi's indication for chemo-refractory patients.[14] The June 4 submission further made clear that the market share comparison used patient data (not direct sales), RJN, Ex. C at 58 of 384 (PDF page), and that there was a critical need for second-line mCRPC therapies (*i.e.*, mCRPC patients require multiple drugs), *id.* at 41–46 (FDA press releases discussing need for and approval of second-line or alternative drug therapies). This latter point was covered by scientific and medical articles and discussed in the '340 Application specification submitted to the PTO and available on PAIR.[15]

Second, Relator contends Defendants should have disclosed that: (1) other non-oral cancer drugs "have been far more successful than Zytiga," SAC ¶87(a); (2) drug-resistant mCRPC patients must frequently switch medications, which "*suggests* that any new mCRPC drug is likely to have some immediate commercial success," *id.* ¶87(b) (emphasis added); and (3) mCRPC drugs "extend a patient's life by a few months, at best" so prednisone's alleviation of abiraterone's side

[13] *See, e.g.*, RJN, Ex. T at 1 (article announcing FDA approval for chemo-naïve market); RJN, Ex. U at 1 (article announcing FDA approval for chemo-refractory market).
[14] *See, e.g.*, RJN, Exs. PP (FDA page for Xtandi), QQ (Approval Letter), RR (Summary Review).
[15] *See, e.g.*, RJN, Ex. V at 170–71 (mCRPC patients often need multiple lines of treatment "due to inherent or acquired resistance" of the disease); RJN, Ex. I at 1–2 (discussing need for multiple treatments and that hormone therapies can be used in addition to local therapies); RJN, Ex. KK at 16–18 (discussing that resistance to abiraterone and enzalutamide is typically developed and patients can switch to another androgen-receptor targeted drug).

effects "may not" factor in the decision to take Zytiga, *id.* ¶87(f). According to Relator, disclosing these "facts" would have shown that Zytiga's commercial success was attributable to abiraterone's anti-cancer properties and not the claimed invention.[16] Whatever their alleged import, the underlying facts were disclosed in the June 4 submission[17] and discussed in scientific articles.[18]

Lastly, Relator alleges Defendants should have disclosed certain competitive advantages unrelated to the claimed invention that contributed to Zytiga's commercial success: (1) Zytiga "does not sequence well" with Xtandi and therefore had a commercial edge by launching first, SAC ¶87(c); and (2) Zytiga has lower toxicity, was cheaper, and offered a more convenient method of administration than its competitors, *id.* ¶87(d), (g)–(h). Again, these facts were publicly disclosed. The sequencing relationship was the subject of scientific study and publicly discussed in medical publications.[19] Abiraterone's "relatively low toxicity profile" was disclosed in an article included with the '340 Application,[20] the American Urology Association's 2013 guidelines[21] (referenced in SAC ¶87(d)), and readily inferred from Zytiga being a hormone-based therapy, which are known to be less toxic than chemotherapies.[22] The 2013 price points for Zytiga, Xtandi,

[16] Relator's allegations misunderstand what J&J claimed by the '340 Application, which sought to patent the combination of therapeutically effective amounts of both abiraterone and prednisone to treat cancer. RJN, Ex. B. In other words, the '340 Application claimed methods of using a combination therapy in which both abiraterone and prednisone contributed to the anti-cancer effects distinct from the use of abiraterone by itself.
[17] J&J provided information on the drug-resistant nature of mCRPC and the value of second-line therapies. RJN, Ex. C at 41–46 of 384 (PDF page). The FDA press releases J&J submitted also provide the "median overall survival" rate for patients taking the mCRPC drugs. *Id.* at 41, 45.
[18] The success of non-oral cancer drugs has been publicly discussed. *See, e.g.*, RJN, Ex. II at 1 (discussing the successful launch of intravenous cancer drug Avastin). The drug-resistant nature of prostate cancer is well documented. *See, e.g.*, RJN, Ex. W at 1–2 (discussing prostate cancer's "resistance to anti-androgen therapies"); RJN, Ex. X (same). Zytiga's effect in prolonging survival is also well disclosed in the media. *See, e.g.*, RJN, Ex. Y at 2 (article).
[19] *See, e.g.*, RJN, Ex. Z (scientific article) (noting an abiraterone (Zytiga)-to-enzalutamide (Xtandi) sequence "might have more favorable efficacy" than an enzalutamide-to-abiraterone sequence); RJN, Ex. X at 1 (discussing cross-resistance of abiraterone and enzalutamide).
[20] RJN, Ex. O at 46. The '438 Patent lists this article as disclosed. *See* RJN, Ex. B at 2.
[21] RJN, Ex. G at 435 (American Urology Association 2013 Guideline).
[22] *See* RJN, Ex. AA at 1 (doctors typically use hormone therapy as a first-line treatment "because hormone therapy is less toxic and has fewer side effects than chemotherapy").

and Jevtana were also publicly available,[23] as was each drug's method of administration.[24] Publicly sourced articles have also documented a preference for oral over intravenous therapies.[25]

In sum, while Defendants dispute Relator's claimed omissions, it is undisputed that each of these "facts" was publicly available to anyone who might go searching for it.

3. The Allegations And Transactions Described In Relator's Complaint Are "Substantially The Same" As The Publicly Disclosed Information.

The SAC does not rely on any non-public information and is virtually indistinguishable from the prior disclosures. *See U.S. ex rel. Yagman v. Mitchell*, 711 F. App'x 422, 423–24 (9th Cir. 2018). When information is already publicly disclosed, "the mere application of experience or deductive skills to such information or the addition of another allegation to the already articulated accusation of fraud does not create a new, non-barred, claim of fraud." *Omnicare*, 903 F.3d at 89–90. Relator's molding previously disclosed facts into his fraud narrative does not launder them of prior disclosure. *See id.* at 89; *see also A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1245 (9th Cir. 2000). Rather, his claims are barred because they are "supported by" and "substantially similar to" the described public disclosures. *Omnicare*, 903 F.3d at 84.

B. Relator's Allegations And Transactions Were Disclosed In Enumerated Channels.

To trigger the disclosure bar, the pertinent information must have been disclosed via one of three statutorily-delineated channels. "By dividing these activities into [three] categories,

[23] *See* RJN, Ex. BB at 3 ("Zytiga costs $5,500 a month, while Xtandi gets $7,450 a month."); RJN, Ex. CC at 2 (Jevtana "costs about $8,000 every three weeks").

[24] Each drug's contemporaneous commercial webpage shows that the methods of administration for Zytiga and its competitors were fully disclosed. *See* RJN, Ex. DD at 2, 4 (Zytiga's website as of Oct. 15, 2017) (Zytiga is an "[o]ral, once-daily" "prescription medicine that is used along with prednisone"); RJN, Ex. EE at 1 (Xtandi's website as of Oct. 6, 2017) ("Swallow Xtandi capsules whole."); RJN, Ex. FF at 1 (Jevtana's website as of Oct. 5, 2017) ("Jevtana is an infusion medicine."). This was also disclosed in scientific and news articles. *See* RJN, Ex. LL at 1 ("Zytiga tablets should be swallowed whole with water."); RJN, Ex. MM at 2 ("Xtandi, an androgen receptor inhibitor, is taken orally, once a day."); RJN Ex. NN at 2 ("Sanofi sells Cabazitaxel injection under brand name Jevtana.").

[25] *See, e.g.*, RJN, Ex. R at 3 ("Oral formulations can be favourable over injections and infusions.").

Congress demonstrated that, despite the similarities between" these subsections, "it intended to distinguish between these … groups of conduct in some way." *United States v. Fiorillo*, 186 F.3d 1136, 1147 (9th Cir. 1999) (per curiam). In 2010, Congress refined these categories to better capture circumstances where the Federal Government is more likely to have been put on notice of the facts illuminating the alleged fraud. To qualify, a disclosure must have been made "(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media." 31 U.S.C. §3730(e)(4)(A) (footnote omitted).

Channel (i) covers adversarial adjudicative proceedings wherein the Government is a party appearing before a neutral decision maker. *Id.* §3730(e)(4)(A)(i). In the 2010 Amendments, Congress specified that the hearing must be "Federal" and the Government be a "party." The "party" requirement underscores this channel's focus on *adjudicative* proceedings. *See* Black's Law Dictionary, *Party* (11th ed. 2019) ("one by or against whom a lawsuit is brought; anyone who both is directly interested in a lawsuit and has a right to control the proceedings, make a defense, or appeal from an adverse judgment."); *see also In re Trs. Established Under the Pooling & Serv. Agreements*, 241 F. Supp. 3d 905, 918 (D. Minn. 2017). Together, the 2010 changes excluded state and other proceedings where the Federal Government was less likely to have notice of the disclosed facts because it was not a party.

Channel (ii) covers non-adjudicative, administrative hearings. In 2010, Congress replaced the words "administrative … report" with "other Federal report," again removing state proceedings, and revising this channel to cover "a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation." 31 U.S.C. §3730(e)(4)(A)(ii) (footnote omitted). The words "or other" trigger the cannon of *ejusdem generis*, *see Yates v. United*

States, 574 U.S. 528, 544–45 (2015) (plurality opinion), underscoring that this channel covers Federal activities similar to "congressional" or GAO reports, hearings, audits, or investigations. Channel (ii) thus describes non-adjudicative, administrative activities wherein the Government plays an investigative or inquisitorial role, gathering, analyzing, and/or releasing information to the public.

Although seemingly similar, channels (i) and (ii) differentiate between the Government's adjudicative and fact-gathering roles by contemplating distinct types of activities based on the degree and nature of its involvement. In channel (i), the Government is party to an adversarial adjudication, whereas in channel (ii), the Government gathers and disseminates information. That the 2010 Amendments required the Government to be a party to the hearings covered in channel (i) but not to the hearings covered by (ii) reflects that difference. The Government plays a role in every Federal adjudicative hearing inasmuch as it provides a forum and a judge; but judges often see only the facts the parties present, and in many matters never adjudicate the facts at all. Thus, the "party" requirement in channel (i) sweeps in only adjudicative hearings where the Executive Branch is motivated to develop the facts, as a litigant. In the hearings captured by channel (ii), however, the Executive Branch drives the inquisitorial information-gathering and dissemination. Thus, the "party" restriction Congress added to channel (i) was unnecessary for the proceedings covered in channel (ii), because there the United States will likely learn the salient facts.

Lastly, *Channel (iii)* bars *qui tam* lawsuits based on facts disclosed in "the news media." 31 U.S.C. §3730(e)(4)(A)(iii). News media traditionally has been broadly construed both within and outside the FCA context, and Congress did not change this provision in the 2010 Amendments. *See Graham Cnty.*, 559 U.S. at 290 ("news media" has "a broad[] sweep"); *Lovell v. City of Griffin*, 303 U.S. 444, 452 (1938) (recognizing "liberty of the press" protects "every sort of publication

which affords a vehicle of information and opinion," not just "newspapers and periodicals").

The facts underlying Relator's allegations and transactions were previously and publicly disclosed through one or more of these channels.

1. Relator's Claims Were Publicly Disclosed Through Federal IPR Hearings.

IPR proceedings come comfortably within the enumerated disclosure channels. Congress established IPRs in the America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011). IPRs provide an alternative, expedited forum for testing patents outside of Federal courts. Established after the 2010 FCA Amendments, IPRs are a unique hybrid of adjudicative and administrative hearings that bring them within both channel (i) and channel (ii). Consistent with the goal of the 2010 refinements, IPRs put the Government squarely on notice of facts disclosed therein.

An IPR is "in key respects a proceeding between the government and the patent owner," *Regents of Univ. of Minn. v. LSI Corp.*, 926 F.3d 1327, 1339 (Fed. Cir. 2019), *cert. denied*, 140 S. Ct. 908 (2020), as the Government plays a key substantive role. Most importantly, no IPR petition may proceed until the PTO Director elects to institute it based on the likelihood of success. *See* 35 U.S.C. §314(a). As with prosecutorial discretion, this decision is not subject to judicial review. *See Oil States Energy Servs. LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1371, 1378 n.5 (2018); 35 U.S.C. §314(d). Once the Director institutes an IPR, it is usually pressed by the private petitioner. However, if the petitioner stops participating, the PTAB may prosecute the IPR to decision, and the PTO can defend PTAB decisions on appeal. *Minnesota*, 926 F.3d at 1336-37; 35 U.S.C. §§143, 314(a), 317(a). The Government thus plays a "central role" in every IPR and does far more than provide a neutral forum to adjudicate private rights. *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018). Because the Government is actively invested in the merits of an IPR—so much so that a Federal officer must decide whether an IPR may be prosecuted at all and can continue to develop the facts on its own without the aid of a

private party—it is akin to a civil litigant, on notice of the asserted facts and allegations.

The Federal Circuit has also described an IPR as "an agency enforcement action instituted by the PTO 'upon information supplied by a private party' rather than civil litigation." *Minnesota*, 926 F.3d at 1339.[26] Akin to a whistleblower program, the Government learns information from a private person and elects whether to proceed based upon it. The PTO's discretion extends to "determin[ing] that for reasons of administrative efficiency an IPR will not be instituted, as agencies generally are free, for similar reasons, to choose not to initiate enforcement proceedings." *Mylan Labs. Ltd. v. Janssen Pharm., N.V.*, 989 F.3d 1375, 1382 (Fed. Cir. 2021) (citing *Heckler v. Chaney*, 470 U.S. 821, 830–32 (1985)). In an IPR, the PTO "act[s] as the United States in its role as a superior sovereign to reconsider a prior administrative grant." *Saint Regis*, 896 F.3d at 1329. As such, the PTO receives and investigates the pertinent facts related to its initial grant of the patent. Because of the Federal Government's involvement, patent holders otherwise entitled to sovereign immunity in private litigation do not have that same privilege in an IPR. *See Minnesota*, 926 F.3d 1327 (state sovereign immunity); *Saint Regis*, 896 F.3d 1322 (tribal sovereign immunity). The PTO must report facts disclosed in an IPR on the PTAB's online, public IPR docket. *See* 35 U.S.C. §316(a)(1). Because the PTO conducts an inquisitorial proceeding in the United States' sovereign capacity to aid its administration of patent-related laws and policy, the Government possesses, and is charged with notice of, facts relevant to that proceeding. Accordingly, an IPR also constitutes an "other Federal" proceeding that results in a "report," often includes a

[26] That Congress did not authorize the Government to petition for an IPR, *see Return Mail, Inc. v. U.S. Postal Serv.*, 139 S. Ct. 1853, 1857 (2019), does not minimize the PTO's significant involvement in the rest of the enforcement action. *See* Brief for Fed. Resp't at 25, *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365 (2017) (No. 16-712) ("[A]lthough private challengers may assist the Board by identifying questionable patents…, the Board's role is to protect the public interest in the integrity of existing patents, not to determine the respective rights of the patentee and challenger….").

"hearing,"[27] and is readily classified as an "investigation," in channel (ii). *See* §3730(e)(4)(A)(ii).

The only court to address this issue concluded that IPRs qualify as a disclosure channel. That court observed that Relator "is also a far cry from the quintessential whistleblower plaintiff," and found his allegations "were all disclosed in the PTAB proceedings." *Silbersher v. Valeant Pharm. Int'l, Inc.*, 445 F. Supp. 3d 393, 402, 404 (N.D. Cal. 2020). The court explained "[t]he PTAB is an adjudicative body within the USPTO that conducts IPR trials and other proceedings before administrative patent judges. This functionality falls squarely within the plain meaning of a federal hearing." *Id.* at 406 (citation omitted).[28]

Although novel, IPRs bear the hallmarks of a "hearing" under channels (i) and (ii). And the Federal Government is clearly put on notice—that is, the clear purpose of the bar is met.

2. Relator's Claims Were Publicly Disclosed Through "Federal Reports."

In addition to public IPR petitions, Relator relies heavily on patent prosecution materials published through the PTO's Patent Application Information Retrieval ("PAIR") system—a qualifying "Federal report" under channel (ii).

Federal law requires the PTO to "publish" patent applications, which it does via its Public PAIR database along with the agency's analysis of and action on the application. *See* 35 U.S.C. §122(b)(2)(B)(i), 37 C.F.R. §1.211;[29] *Fleetwood Grp., Inc. v. Albert Hall Meetings, Ltd.*, No. 6:06-

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[27] *See A-1 Ambulance Serv., Inc*, 202 F.3d at 1244 ("Hearing in this context is synonymous with proceeding, and encompasses publicly-filed documents even [without] a hearing." (cleaned up)).

[28] The district court in Relator's second California *qui tam* disagreed with *Valeant* and rejected its application to patent prosecution hearings and PAIR filings. *See Silbersher v. Allergan Inc.*, No. 18-CV-03018 JCS, 2020 WL 7319407, at *18 (N.D. Cal. Dec. 11, 2020). Although *Allergan* opined that "the PTAB proceedings in *Valeant*," *id.* at *25, were not Federal hearings under the public disclosure bar, that reasoning was dicta; the court had previously determined that the IPRs there did not disclose the fraud allegations, *id.* at *17, and thus did not analyze whether IPRs qualify as a disclosure channel. Nor did that court consider the additional arguments presented herein. *See id.* at *9–16.

[29] Once published, patent applications are publicly available through Public PAIR. *See* PTO, *Published Patent Application Access and Status Information Sheet for Members of the Public*, https://www.uspto.gov/patents-application-process/patent-search/published-patent-application-

cv-859-Orl-19JGG, 2007 WL 9723102, at *2 n.2 (M.D. Fla. June 20, 2007).

In *Schindler Elevator Corp. v. United States ex rel. Kirk*, in concluding that a FOIA response was a qualifying "federal report," the Supreme Court held a "report" is "something that gives information" or "a notification" or "an official or formal statement of facts or proceedings." 563 U.S. 401, 407–08 (2011) (alterations omitted). PAIR does exactly that—it reports information on patent application filings, including the patent prosecution itself, and notifies the public about those filings and the PTO's actions in response. Like FOIA, PAIR is the Government's chosen mechanism for publishing records in its possession, including those it is statutorily obligated to publish eighteen months after the application's filing. *See* 35 U.S.C. §122(b)(1)(A), 37 C.F.R. §1.211.

The only court to consider this issue incorrectly held that patent prosecution histories on PAIR are not subject to the public disclosure bar. *See Allergan*, 2020 WL 7319407, at *18. That court first concluded, correctly, that patent prosecutions are *ex parte* agency proceedings not within channel (i). *Id*. at *33. But it then misapplied the 2010 Amendments, construing the Federal Government party requirement, which Congress only added to channel (i), as also constraining the scope of channel (ii). *Id.* at *34. In so doing, the *Allergan* court violated the basic canon that a statute must be read harmoniously, giving meaning to the entire text, without adding or subtracting words. *See, e.g.*, *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988); *Birdman v. Off. of the Governor*, 677 F.3d 167, 176 (3d Cir. 2012).

The *Allergan* court also adopted too miserly a construction of "report." With respect to *Schindler Elevator*, it noted, an official determines which documents to include in a FOIA

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access-and-status-information (last modified June 7, 2017) (directing the public to PTO website for patent application publications). The '340 Application was published as of June 16, 2011. *See* RJN, Ex. OO, Notice of Publication. Subject to certain exceptions not applicable here, documents submitted in connection with the '340 Application were thereafter viewable on Public PAIR.

response, whereas on PAIR, patent filings are published by statutory command. 2020 WL 7319407 at *35. This is incorrect twice over. First, preparing a FOIA response is no less ministerial than publishing a patent application. That one is done automatically by a computer while the other requires a human to determine which documents FOIA requires to be made public makes the latter no more an act of discretion. Second, neither *Schindler Elevator* nor the FCA itself restricts "federal reports" to documents reflecting an official's judgment, discretion, or curation. As held in *Schindler Elevator*, a "report" is "something that gives information" or "a notification" or "an official or formal statement of facts or proceedings," and Congress has not since changed that determination.

Applying the bar in *Schindler Elevator*, the Court observed "anyone could identify a few regulatory filing and certification requirements, submit FOIA requests and then [have] filed [relator's] suit." 563 U.S. at 413 (noting the case was "a classic example of the 'opportunistic' litigation that the public disclosure bar is designed to discourage"). Relator's conduct here is no different. PAIR reports are fundamentally the sort of public disclosure Congress sought to prevent from supporting *qui tam* claims.

3. Relator's Claims Were Publicly Disclosed Through "News Media."

Relator's essential factual transactions were also reported in various qualifying "news media." 31 U.S.C. §3730(e)(4)(iii). "News media" comprises a broad range of publications that goes beyond newspapers and periodicals. *See, e.g.*, *Moore*, 812 F.3d at 302–03 ("news media" "likely describe[] a multitude of sources that would seldom come to the attention of the Attorney General"); *U.S. ex rel. Repko v. Guthrie Clinic, P.C.*, No. 3:04CV1556, 2011 WL 3875987, at *7 (M.D. Pa. Sept. 1, 2011) ("information in scholarly or scientific periodicals qualifies as news media" (cleaned up)); *U.S. ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 813 (11th Cir. 2015) ("the term [news media] includes publicly available websites").

Numerous courts have ruled "information contained on publicly available websites can be public disclosures within the meaning of the FCA." *E.g. Repko*, 2011 WL 3875987, at *7. Although "not all information in the public domain" falls within this subset, "news media" "at minimum" includes websites where "information provided is to some extent curated …. [and] bears at least some of the 'indicia of reliability or substantiation' common to more traditional news media sources." *U.S. ex rel. Customs Fraud Investigations v. Victaulic Co.*, No. 13-2983, 2014 WL 4375638, at *9–10 (E.D. Pa. Sept. 4, 2014). For instance, "news media" encompasses targeted or curated sources of information including the scholarly journals, scientific studies, business articles, competitor websites, and data collected and disseminated by the Government through its websites and databases that disclose the transactions that comprise Relator's allegations. *See supra* I.A.3; *Plavix I*, 123 F. Supp. 3d at 596 (online publications are "news media"); *Repko*, 2011 WL 3875987, at *7 (scholarly or scientific periodicals qualify).

Anyone with internet access could have compiled the articles and webpages that identify the transactions underlying Relator's case. The public disclosure bar seeks to prevent exactly that.

C. Relator Is Not An Original Source.

A relator who relies on publicly disclosed facts may avoid the public disclosure bar only by qualifying as an "original source"—someone who (1) "prior to a public disclosure … voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based" or (2) "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing" the *qui tam* lawsuit. 31 U.S.C. §3730(e)(4)(B). Relator is neither.

As an initial matter, Relator has not pled any facts demonstrating that his voluntary disclosures to the Government pre-date the foregoing public disclosures. *Compare* SAC ¶¶16–17 (pleading voluntary disclosures were made in November 2, 2018 and June 5, 2019) *with* RJN, Exs.

C–FF, II–NN (all disclosures were made prior to 2018).

Furthermore, Relator pleads nothing to support his original-source status beyond his own say-so. *See* SAC ¶¶16–17. The SAC pleads no facts independent of or that materially add to the public disclosures. *See In re Plavix Mktg., Sales Practices & Prod. Liab. Litig.*, 315 F. Supp. 3d 817, 824–25 (D.N.J. 2018) (*Plavix III*), *vacated on other grounds*, 974 F.3d 228 (3d Cir. 2020). Relator fails to contribute information that is "distinct from what was publicly disclosed, that adds in a significant way to the essential factual background: the who, what, when, where, and how of the events at issue." *Moore*, 812 F.3d at 307. Relator claims he independently provided facts relating to the approval status of Xtandi and to Zytiga's commercial success, but he fails to specify those facts. SAC ¶17. Instead he gestures vaguely to unspecified "independent research and investigation" without identifying the nature of his research or investigation or how it supplemented the prior public disclosures. *See id.* ¶16.[30] *See U.S. ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 118–19 (W.D. Pa. 2006) (court cannot assume facts not pled).

Far from being an original source, Relator copied facts asserted by others in different contexts—facts which have been widely publicized through enumerated channels. Relator's parasitic claims should be dismissed. *See U.S. ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh*, 728 F. App'x 101, 103 (3d Cir. 2018) ("[A] relator should not be able to profit from a *qui tam* case that it predicates on information developed by other parties.").

II. RELATOR FAILS TO PLEAD ESSENTIAL ELEMENTS OF HIS CLAIMS

An FCA complaint must plead "four elements: falsity, causation, knowledge, and materiality." *U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017). And

[30] The lack of specifics in the SAC is particularly telling given that when repleading Relator had the benefit of J&J's first motion to dismiss, which included the numerous channels and sources by which the claimed facts and allegations were previously disclosed.

because the FCA sounds in fraud, each element must be pleaded with particularity, Fed. R. Civ. P. 9(b), containing "all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue," *Moore*, 812 F.3d at 307 (quoting *In re Rockefeller Ctr. Props., Inc. Securities Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)). Relator fails to plead sufficiently falsity or materiality.[31]

A. Relator Fails To Plead A False Claim Or A False Statement Material To A False Claim.

A false claim is the *sine qua non* of FCA liability. *Bartlett*, 234 F.R.D. at 124. Courts recognize three theories of falsity: (1) factual falsity; (2) legal falsity (express or implied); and (3) promissory fraud. *See Petratos*, 855 F.3d at 487. Regardless of the alleged theory, "FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government." *See United States v. Care Alternatives*, 952 F.3d 89, 97 (3d Cir. 2020), *cert. denied*, 2021 WL 666386 (Feb. 22, 2021). Although not entirely clear, the SAC appears to allege implied false certification or promissory fraud. It fails to plead falsity adequately under either.

1. Relator Fails To Plead An Implied False Certification Connected To A Claim For Reimbursement.

The FCA does not reach all false statements made to the Government, but rather only those statements material to the presentation of a claim for payment. *In re Plavix Mktg., Sales Practice & Prods. Liab. Litig.*, 332 F. Supp. 3d 927, 951 (D.N.J. 2017) (*Plavix II*). Relator contends without elaboration that Defendants "expressly and implicitly" certified—to an unidentified person at an unidentified time—that Zytiga's price was "fair and reasonable" or "not tainted by fraud." SAC ¶110. But Relator has not identified any false statement or misleading representation in the

[31] For the same reasons Relator fails to plead a cause of action under the FCA, he also fails to assert claims under each of the Plaintiff states' statutes. *See* SAC Claims for Relief II-XXXI.

presentation of a *claim* for payment or approval to a Government payer.[32]

If "a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for [implied-false-certification] liability if they render the defendant's representations misleading with respect to the goods or services provided." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016). An impliedly false claim has two conditions, both of which are missing here: "first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001; *see also United States v. Eastwick Coll.*, 657 F. App'x 89, 94 (3d Cir. 2016).

Post-*Escobar* decisions recognize the importance of "specific representations" to anchor the implied certification theory. *See U.S. ex rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1017–18 (9th Cir. 2018); *U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 37 (1st Cir. 2017); *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016); *U.S. ex rel. Smith v. Wallace*, 723 F. App'x 254, 256 (5th Cir. 2018) (per curiam). Courts in this circuit have likewise applied *Escobar*'s two-pronged analysis. *See Plavix II*, 332 F. Supp. 3d at 939; *U.S. ex rel. Bahnsen v. Bos. Sci. Neuromodulation Corp.*, No. CV 11-1210, 2017 WL 6403864, at *7 (D.N.J. Dec. 15, 2017); *Pink v. Khan*, No. CV 13-4924, 2018 WL 5831222, at *5 n.11, *6 n.14 (E.D. Pa. Nov. 7, 2018); *United States v. Select Specialty Hosp.-Wilmington, Inc.*, No. 1:16-CV-347, 2018 WL

[32] To the extent Relator asserts an express-false-certification theory, his effort fails. Relator nowhere describes the details of any allegedly offending claim for reimbursement submitted to a Government payer, let alone any specified certification or representation concerning Zytiga's price. *E.g. Plavix II*, 332 F. Supp. 3d at 939.

1568874, at *4 (D. Del. Mar. 30, 2018).[33]

Relator fails to meet his burden. The lack of specifics concerning both the claims themselves and any attendant, let alone material, regulatory requirements precludes any showing that Defendants (1) made or caused to be made any specific representations concerning Zytiga, which (2) were misleading half-truths due to some statutory, regulatory, or contractual non-compliance. Indeed, Relator fails to identify *any* specific representation made in connection with a claim for payment at all.

Courts in this Circuit have been loath to expand the implied-false-certification theory in the healthcare context in the absence of specific representations. *See U.S. ex rel. Jackson v. DePaul Health Sys.*, 454 F. Supp. 3d 481, 500 (E.D. Pa. 2020) (citing *Eastwick Coll.*, 657 F. App'x at 94). "[T]o the extent there is some doubt about the availability of an implied-certification-without-representation theory, the Third Circuit has found in a different situation that expansion of the implied certification theory is especially not appropriate in the healthcare context." *Id.* (citing *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 307 (3d Cir. 2011), *abrogated on other grounds by Escobar*, 136 S. Ct. at 1989). Similar caution is warranted here.

2. Relator Fails To Plead A False Statement In Connection With Drug Pricing.

Failing to plead specifics in connection with the submission of a claim for payment, Relator instead makes allegations concerning the negotiation of Zytiga's federal-list price. Specifically, Relator attacks Zytiga's federally agreed price as unfair and unreasonable because J&J's pricing data reflected Zytiga's patent exclusivity. SAC ¶¶115, 117.

[33] One decision in this District did permit a relator to proceed with implied false certification in the absence of specific representations on the theory that "all claims for payment implicitly represent that the billing party is legally entitled to payment." *U.S. ex. rel. Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392, 407 (D.N.J. 2019) (emphasis omitted) (quoting *Escobar*, 136 S. Ct. at 2000). That position, however, contradicts views by the Supreme Court and Third Circuit that the FCA is not intended to police all regulatory non-compliance. *Escobar*, 136 S. Ct. at 2003; *Wilkins*, 659 F.3d at 307.

Relator's claim, however, misunderstands the drug contracting process and severs the phrase "fair and reasonable" from its regulatory moorings. In this context, "fair and reasonable" is not a representation drug manufacturers make to the Government. Nor does that phrase invite a freewheeling inquiry into the subjective reasonableness of a drug's price or a manufacturer's conduct. Rather, it refers to a specific, objective comparison by the Government itself between the supplier's commercial price and its listed Government price.[34] That relationship defines how much the Government pays for a drug, and the discount formula is unaffected by patent exclusivity.

The pricing process is not an open-ended negotiation that includes qualitative statements about a drug's price. To the contrary, as described in the Solicitation Relator references, SAC ¶114, the VA operates a structured review process designed in part "to ensure … the Government is receiving a fair and reasonable price." RJN, Ex. H at CP-11; *see also* 48 C.F.R. §8.404(d) (prices listed on the FSS have been determined to be "fair and reasonable"). "Contracting Officers determine whether prices are fair and reasonable by comparing the prices/discounts that a company offers the government with the prices/discounts offered to commercial customers." RJN, Ex. H at CP-8. Each quarter, manufacturers provide the VA with the AMP, which is used to calculate the FCP. SAC ¶112. Manufacturers also periodically provide the VA with commercial pricing information, Most Favored Customer information, and Tracking Customer information to allow VA contracting officials to ensure that the prices offered to the Government remain "fair and reasonable" throughout the contract term. *Id.*; RJN, Ex. H at 53. Whether a government price is "fair and reasonable" is a conclusion drawn by the Government itself when comparing government

[34] Relator's attempt to supply a meaning for the term "fair and reasonable" not found in any authority he cites, *e.g.*, SAC ¶117, is a legal conclusion the Court need not accept as true for purposes of this motion to dismiss. *See Druding v. Care Alts., Inc.*, 164 F. Supp. 3d 621, 626 (D.N.J. 2016); *U.S. ex rel. Jersey Strong Pediatrics, LLC v. Wanaque Convalescent Ctr.*, No. 14-6651, 2017 WL 4122598, at *2 (D.N.J. Sept. 18, 2017).

and commercial prices. RJN, Ex. H at CP-8. Manufacturers must present accurate data, but the contracting officer decides whether a price is "fair and reasonable." *Id.* And although the Government may access certain manufacturer records to "verify the pricing, sales and other data related to the supplies or services proposed in order to determine the reasonableness of the price(s)," that "[a]ccess does not extend to [the] offeror's cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace." *Id.* at 53.

In other words, Contracting Officers do not consider *how* a manufacturer arrived at the commercial price—only *whether* the proposed Government pricing compares favorably to it. The pricing process is a mathematical calculation based on a market price, performed by an officer who makes the comparison and assesses whether the price is "fair and reasonable." The manufacturer does not make its own representation to that effect when it supplies the officer with the relevant data or any time thereafter.

Relator does not plead that Defendants submitted incorrect commercial pricing data to the VA, misidentified the tracking customer, or made any other incorrect representation to the VA or to any other Federal healthcare agency. Nor does he allege that the discounts to which the Government agreed were not "fair and reasonable" as determined by the VA. Relator claims instead that the pricing information carried an implicit certification that it was not "unlawfully inflated through the exclusion of competitors," SAC ¶115, or "the product of an unlawfully extended patent monopoly," *id.* ¶117. But Relator cites no binding authority—nor are Defendants aware of any—holding that a drug's patent prosecution history, or the PTO's reasons for issuing a patent, are incorporated—expressly or implicitly—into the Government's "fair and reasonable"

assessment under the Solicitation.[35] Relator's attempt to pour substantive meaning into the GSA's pricing requirements contradicts the agency's authoritative construction of its statutory and regulatory charges, as set forth in the detailed Solicitation, which does expressly incorporate other regulatory representations, such as whether the manufacturer has complied with the Trade Agreement Act, or has an NDA or ANDA on file. *See* Solicitation, RJN Ex. H at 2, 7. Any alleged "implied" certification about price reads terms into the contracting process that are not there.

Relator's theory of falsity is shockingly broad. His construction of the GSA's "fair and reasonable" requirement would swallow *any* regulatory or statutory requirement that might affect a product's price no matter how attenuated from the claim-submission process. In the patent context alone, this would trigger FCA liability any time a patent is called into question through an infringement action or an IPR, and, in all likelihood, on a much more frequent basis separate and apart from those proceedings. Relator's theory would vastly expand application of the implied certification theory in the healthcare context, *Wilkins*, 659 F.3d at 307; *Jackson*, 454 F. Supp. 3d at 500, and unleash the FCA as an "all-purpose antifraud statute," *Escobar*, 136 S. Ct. at 2003. The Court should thus dismiss those claims grounded in an implied false-certification theory.

3. Relator Fails To Plead A Promissory Fraud Theory Of Liability.

The SAC separately asserts the alleged misconduct before the PTO amounted to an "upstream fraud" that "taints claims for payment later submitted to the government," SAC ¶¶106–

[35] The *Allergan* court's contrary ruling, that in submitting pricing information, defendants necessarily impliedly certified that their prices were "fair and reasonable," which in turn "misleadingly suggested that they held valid patents on those drugs that allowed them to charge the government higher prices as a result of the monopolies they held on them," *Allergan*, 2020 WL 7319407, at *37, lacks persuasive value. That opinion ignores the GSA and VA's own construction of "fair and reasonable," and does not explain how pricing agencies ever consider patent validity or status. Although the court indicated the Government may examine the fair-and-reasonable price and "may rely on those prices when there is 'adequate price competition,'" *see id.* (quoting 48 C.F.R. §15.402(a)(2)(i)), §15.402(a) "do[es] not apply to … orders placed against Federal Supply Schedules contracts." *See* 48 C.F.R. §8.404(a).

107, a theory that appears to be rooted in promissory fraud. A false claim may be established through the contract-law theory of fraud in the inducement. *See U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 542 (1943). This is a "narrow, third category of false claims" under which FCA liability can attach to payments made pursuant to a fraudulently induced *contract*. *Plavix II*, 332 F. Supp. 3d at 939 (citing *United States v. Veneziale*, 268 F.2d 504, 505 (3d Cir. 1959)). "To prevail on a fraudulent inducement claim under the [FCA], a plaintiff must show that (1) there was a knowingly false or fraudulent statement; (2) that the statement was material; and (3) that it caused the government to pay out money or to forfeit moneys due (*i.e.*, a 'claim')." *U.S. ex rel. Thomas v. Siemens AG*, 593 F. App'x 139, 143 (3d Cir. 2014).

Relator's variation on promissory fraud is not cognizable under the FCA. When Congress codified *Hess*, it limited it "to claims 'under a contract, loan guarantee, or other agreement.'" *See Plavix II*, 332 F. Supp. 3d at 952 (quoting S. Rep. No. 99-345, at 9 (1986)). This limitation flows from the theory's contract roots, and the Third Circuit has not applied promissory fraud outside the contractual context. *Id*. In *Plavix II*, this Court expressly rejected expanding the theory to allegations, like Relator's, that arise "in the context of non-contract interactions with government regulatory bodies." *Id*. The "direct causal connection" between "contracts induced by fraud and claims submitted under those contracts" prevents this theory from converting the FCA into an "all-purpose antifraud statute." *Id.* at 953. Accordingly, the alleged fraudulent act must be critical to the inducement of the contract. *E.g.*, *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016) (false statement made to FDA to secure product approval too attenuated); *In re Baycol Prods. Liab. Litig*, 732 F.3d 869, 876 (8th Cir. 2013) (misrepresentations after government requested additional information about a drug supported fraud in the inducement); *see also United States v. Wavefront LLC*, No. 20-5094, 2021 WL 37539, at *10 (D.N.J. Jan. 5, 2021).

As this case illustrates, the requisite causal connection is missing from non-contract situations because the purported fraud does not "give rise to the claims submitted for payment to the government." *Plavix II*, 332 F. Supp. 3d at 952. Relator's claims of taint and causation notwithstanding, SAC ¶¶44 107, issuance of the '438 Patent did not induce the Government to list Zytiga on the FSS or to reimburse claims. Procuring a patent is not "integral" to claims for payment under Federal healthcare programs—claims that might occur years later after passing through several other regulatory schemes.

The FCA is not "a blunt instrument to enforce compliance with all … regulations." *Wilkins*, 659 F.3d at 307. Yet to "embrac[e] Relator's theory would be a step toward bringing all misrepresentations to government bodies within the purview of the FCA." *Plavix II*, 332 F. Supp. 3d at 953. And it would work a massive expansion of the "narrow" theory recognized in *Hess*. Nothing in that case or later cases applying promissory fraud supports the notion that *any* prior-in-time conduct—no matter how remote—can support subsequent FCA liability. The Government has acknowledged that "at some point, the causal chain can become so attenuated that the subsequent claim for payment no longer retains the 'taint' of the defendant's initial fraud." Br. for the U.S. as *Amicus Curiae* at 20, *D'Agostino*, 845 F.3d 1 (No. 16-1126) (quoting *Hess*, 317 U.S. at 543); *cf. U.S. ex rel. Promega Corp. v. Hoffman-La Roche Inc.*, No. 03-1447-A, slip op. at 5 (E.D. Va. Sept. 29, 2004) ("misrepresentations" to the PTO years prior were "disconnect[ed]" from "invoices submitted to the Government" and failed to state an FCA claim) (attached hereto as Appendix B).

The *Allergan* court's contrary conclusion is not persuasive. That decision turned on two Ninth Circuit cases, which are not binding here and do not compel *Allergan*'s conclusions. Both turn on misrepresentations that were material to payment eligibility. But neither Zytiga's patent

status nor its pricing has anything to do with its eligibility for Federal reimbursement.

In *United States ex rel. Campie v. Gilead Sciences, Inc.*, for example, the court devoted just two paragraphs to promissory fraud after first determining the relator had alleged an FCA claim rooted in express and implied false certification, a factor lacking here. 862 F.3d 890, 902, 904 (9th Cir. 2017). *Campie* is also a poor factual analogue. There, the defendant had secured FDA approval to manufacture a drug using ingredients from specified sources, and its NDA certified as much. *Id.* at 895. Yet it purportedly sold and sought payment for drugs made with ingredients from unregistered sources, and allegedly misrepresented the results of tests conducted on those ingredients. *Id.* at 896. The court equated this conduct to fraud in the inducement, where "liability will attach to each claim submitted to the government *under a contract*, when the contract or extension of the government benefit was originally obtained through false statements or fraudulent conduct." *Id.* at 902 (emphasis added). The grant of eligibility to manufacture the drug was "integral to a casual chain leading to payment." *Id.* at 903. That is, the defendant "lied to the FDA to secure approval"; approval that made it "eligible for government payments." *Id.* at 899.

U.S. ex rel. Hendow v. University of Phoenix is even less relevant. 461 F.3d 1166 (9th Cir. 2006). That case concerned an agreement that required universities "to abide by a panoply of statutory, regulatory, and contractual requirements," including a ban on paying certain incentives to recruiters, to receive certain federal payments. *Id.* at 1168–69. Although the university agreed to comply with the ban, it had no intention of doing so. *Id.* Because the misrepresentation was tied directly to eligibility for payment, the subsequent claims for payment were false.

This case lacks similar causal chains. Relator's claims of fraud turn on statements made to the PTO that have no bearing on the drug's listing on the FSS, let alone decisions to prescribe, or reimburse claims for, Zytiga. Because *Allergan* ignores the doctrinal roots of promissory fraud and

stretched *Campie* and *Hendow* far beyond what they stand for, it lacks persuasive force.

In short, promissory fraud reaches only contracts. And, even if expanded further, at its broadest promissory fraud demands a close causal connection between a false statement made to secure eligibility for a federal benefit and a subsequent claim for payment of that benefit. Alleged misrepresentations to the PTO are entirely separate from the FSS contracting process and cannot "taint" subsequent claims for payment. Manufacturers make no "promises" to the PTO that induce contracts with Federal healthcare programs to plausibly support FCA liability.

Because the alleged fraud resulted in a patent—not a contract—this theory too fails.

B. Relator Fails To Plead Materiality.

The SAC also founders on *Escobar*'s "demanding" materiality standard. *See* 136 S. Ct. at 2003–04; *see also Petratos*, 855 F.3d at 489. Relator has not pled "facts to support allegations of materiality" "with plausibility and particularity." *See Escobar*, 136 S. Ct. at 2004 n.6. For implied false certification, "a plaintiff must show that if the Government had been aware of the defendant's violations of the [relevant] laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims." *Plavix II*, 332 F. Supp. 3d at 939 (quoting *Wilkins*, 659 F.3d at 307). "[S]tatutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment." *Escobar*, 136 S. Ct. at 2001.

Relator's allegations here are conclusory *and* implausible. His allegation that "price … is *per se* material to the government's payment decision," SAC ¶123, is insufficient as a matter of law. *See Escobar*, 136 S. Ct. at 2003. It also falls far short of Rule 8's pleading standard, *Iqbal*, 556 U.S. at 678, let alone the more rigorous requirements of Rule 9(b). And Relator has offered no authority that the "fair and reasonable" standard, even if it meant what he claims, is a condition (express or implied) of payment. *Escobar* further requires Relator to show Defendants *knew* the "fair and reasonable" requirement (as Relator construes it) was material to the payment of a claim.

Escobar, 136 S. Ct. at 1996 (liability may lie only when "the defendant knowingly violated a requirement that the defendant knows is material"). Relator has made no such allegations.[36]

The SAC also lacks any allegations suggesting patent-related misconduct before the PTO ever influences distinct Federal agencies' decisions to pay. For instance, Relator does not allege that any agency stopped reimbursing Zytiga following his allegations. *See id.* at 2003–04. To the contrary, the Government investigated Relator's claims and, as Relator concedes, "*continue[d]* to pay" claims for Zytiga. SAC ¶144 (emphasis added). And Zytiga remains on the FSS to this day.[37] This strongly indicates that the purported violations were not material to the Government's decision to pay. *See Petratos*, 855 F.3d at 490; *cf. D'Agostino*, 845 F.3d at 7.

Other facts indicative of materiality may include "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 94 (3d Cir. 2018) (quoting *Escobar*, 136 S. Ct. at 2003). Relator lists a handful of Government enforcement actions in an effort to show that "[t]he government has repeatedly confirmed, by word and deed, that drug price manipulation is material to its payment decision." SAC ¶126.[38] But Relator does not (and cannot) allege the

[36] *Allergan* similarly flouted *Escobar* by accepting Relator's assertion that "price goes to the 'essence of the bargain,'" without regard to the actual FSS pricing process. 2020 WL 7319407, at *41. *Allergan* speculated as to the Government's views without assessing whether patent validity plays any role in that process. The sole case it cites, *U.S. ex rel. Grubea v. Rosicki, Rosciki & Assocs.*, 318 F. Supp. 3d 680, 701 (S.D.N.Y. 2018), underscores these shortcomings. In *Grubea*, the complaint and opinion exhaustively described the certifications and regulatory requirements that applied to the inflated "price" of claimed reimbursements. *Allergan* ignored this context and is of no help to Relator.

[37] *See* RJN, Ex. SS (FSS for Zytiga 250MG Tab); RJN, Ex. TT (FSS for Zytiga 500MG Tab).

[38] *See* SAC ¶127 (case citation to government-instituted civil litigation against pharmaceutical company for sham litigation that does not reference any decision by government to stop paying for the allegedly artificially priced products); *id.* ¶128 (press release highlighting guilty plea of South Korean companies engaged in bid-rigging to sell military fuel); *id.* ¶129 (civil suit filed against 20 generic pharmaceutical companies for conspiracy to price-fix and market-share); *id.* ¶130 (allegations of price-fixing, bid-rigging, and market allocation that led to deferred prosecution and civil settlement for claims under the FCA and Anti-kickback Statute).

Government has used those tools here, or that those situations involved a refusal to pay claims following an alleged fraud in connection with an underlying patent. None of Relator's examples demonstrates "the effect on the likely or actual behavior of the [Government] of the alleged [patent-related] misrepresentation." *Escobar*, 136 S. Ct. at 2002–03. In fact, Relator has failed to plead that any Federal agency *ever* revisits pricing on account of patent dissolution for any reason. That is what matters for FCA liability.

III. RELATOR FAILS TO PLEAD FRAUD ON THE PTO

The SAC also fails to plead fraud on the PTO. Each of Relator's theories rests on the underlying contention that Defendants obtained the '438 Patent by violating their duty of candor to the PTO. SAC ¶¶63–91; *see Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 974 n.1 (Fed. Cir. 2010); *Pac. Bioscis. of Cal., Inc. v. Oxford Nanopore Techs., Inc.*, No. 17-275-LPS, 2019 WL 668843, at *3 (D. Del. Feb. 19, 2019). To plead an FCA claim predicated on inequitable conduct, Relator must plead it with specificity. Because Relator has not alleged such details, he cannot maintain an FCA claim based on fraud on the PTO.

A relator basing an FCA claim on a predicate legal violation must plead facts sufficient to establish that underlying violation. *See, e.g.*, *U.S. ex rel. Bookwalter v. UMPC*, 946 F.3d 162, 175 (3d Cir. 2019); *U.S. ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, -- F. Supp. 3d --, 2020 WL 6682483, at *7–8 (E.D. Pa. Nov. 12, 2020). For example, where a relator's FCA claim turns on an underlying Stark Act violation, this Circuit first analyzes whether the relator states a claim for the Stark Act violation, which includes satisfying the Act's applicable scienter requirement. *Bookwalter*, 946 F.3d at 169–75; *see also Gohil*, 2020 WL 6682483, at *7–8 (relator must introduce facts sufficient to establish violation of the Anti-Kickback Statute, including applicable scienter requirement). So too with other, non-FCA claims. Fraud on the PTO may support a claim under the Sherman Act, *see Walker Process Equip. Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 178 (1965), but a

plaintiff must plead, then prove, the underlying fraud with particularity, *see TransWeb, LLC v. 3M Innovative Props. Co.*, 16 F. Supp. 3d 385, 407 (D.N.J. 2014), *aff'd*, 812 F.3d 1295 (Fed. Cir. 2016).

Consistent with this well-established principle, Relator must plead facts to plausibly allege a violation of the duty of candor, which is set by the Federal Circuit.[39] Otherwise, litigants—like Relator—could circumvent patent protections by seeking to hold patent owners liable for fraud where no such liability would otherwise exist. Relator has failed to plead such facts.

The duty of candor moreover attaches to *individuals* appearing before the PTO, such as the inventor or those prosecuting the patent—it does not attach to companies. *See* 37 C.F.R. §1.56; *Avid Identification Sys., Inc.*, 603 F.3d at 974 n.1. Courts thus routinely deem allegations that fail to identify individuals as insufficient to establish inequitable conduct. *See, e.g.*, *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329 (Fed. Cir. 2009); *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 307 (D. Del. 2013).

Once he identifies an eligible individual, Relator must demonstrate that she "acted with the specific intent to deceive." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288–90 (Fed. Cir. 2011) (en banc). Specific intent, in turn, requires facts sufficient to show that the individual "knew of the [information being withheld], knew that it was material, and made a deliberate decision to withhold it." *Id.* at 1290. Relator must then further plead that the purported malfeasance was the "but-for" cause for the patent to issue, *id.* at 1291, which requires independent proof of but-for materiality, *see id.* at 1292–93. And, because inequitable conduct sounds in fraud, such claims must be pleaded with particularity, alleging the "who, what, when, where, and how" of the alleged fraudulent conduct. *Exergen*, 575 F.3d at 1327; *see also Eagle View Techs., Inc. v.*

[39] *See Ragner Tech. Corp. v. Berardi*, 324 F. Supp. 3d 491, 506 (D.N.J. 2018) (for purposes of a *Walker Process* claim, Federal Circuit law governs whether the defendant defrauded the PTO).

Xactware Sols., Inc., 325 F.R.D. 90, 93–94 (D.N.J. 2018). Even allegations of specific intent must be "reasonable and drawn from a pleading's allegations of underlying fact." *Exergen Corp.*, 575 F.3d at 1329 n.5. Relator falls far short of these requirements.

First, Relator generally attributes to the named Defendants various misrepresentations and omissions allegedly made to the PTO, SAC ¶¶19–26, 59–91, which is, as a matter of law, insufficient.[40] *Second*, although the SAC added individual inventors of the '438 Patent's claims as well as the prosecuting attorney who signed the June 4 submission, *id.* ¶¶70–71, 91, it makes no attempt to connect the elements of inequitable conduct to any of those individuals. *See Delano Farms Co. v. Cal. Table Grape Comm'n*, 655 F.3d 1337, 1350 (Fed. Cir. 2011) (complaints asserting inequitable conduct must "recite[] facts from which the court may reasonably infer that *a specific individual* both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO" (emphasis added)); *Breville Pty Ltd. v. Storebound LLC*, No. 12-cv-01783-JST, 2013 WL 1758742, at *4–6 (N.D. Cal. Apr. 24, 2013). Instead, Relator attributes the alleged misconduct to the individuals generally as agents. *See* SAC ¶¶69–71, 89, 118. But an agency relationship does not confer individual knowledge of both the facts and the materiality of the alleged facts or omissions on the individuals, and Relator does not separately plead facts implying such knowledge; nor does agency confer a specific intent to deceive the PTO by deliberately withholding that information, and Relator again pleads no facts suggesting such intent. *See Breville Pty. Ltd.*, 2013 WL 1758742, at *6.

[40] And at least some of the alleged misrepresentations are not actionable affirmative or objective statements of fact. SAC. ¶87(a) (opinion statement that Zytiga was the most successful oral oncology launch of all time); *id.* ¶87(b), (f) (Relator speculating as to potential causes of success). Other alleged omissions were not omissions at all, but were disclosed to the PTO in the patent application materials cited in the SAC, such as the existence of the '213 Patent. *See supra* at 11–13. These disclosures in particular undermine any possible intent to deceive, *see Pac. Biosciences*, 2019 WL 668843, at *3, or inference of materiality, *see Therasense*, 649 F.3d at 1291.

Third, Relator pleads no facts linking the effect of each alleged omission or misrepresentation on the patent examiner's evaluation of commercial success, and therefore, the patent's issuance. *Exergen*, 575 F.3d at 1329–30; *see, e.g.*, SAC ¶84(e) (claiming improper market-share metric without evaluating effect on examiner); SAC ¶121 (broadly claiming "[b]ut for Defendants' misrepresentations to the patent office concerning Zytiga's purported commercial success as alleged herein, the Patent Office would never have issued the '438 Patent.").

Even if Relator's unprecedented theory were cognizable (and it is not), because Relator has failed to plead a fraud on the PTO, he has likewise failed to plead an FCA claim.

IV. RELATOR'S CLAIMS AGAINST BTG SHOULD BE DISMISSED FOR ADDITIONAL AND INDEPENDENT REASONS

Relator added BTG as a defendant in the SAC for the first time. The SAC includes only two allegations against BTG (beyond the paragraph identifying BTG as a party): (1) that it co-owns the '438 Patent, SAC ¶¶25, 91; and (2) that it participated in litigation in this Court to enforce that patent, SAC ¶102 n.2. These allegations fail for two additional reasons.

First, the SAC concedes BTG did not prosecute the '438 Patent, which is a necessary predicate of the alleged fraud. Aside from Relator's improper group pleading (*see infra*), the SAC fails to allege BTG knew about the alleged fraud and, thus, fails to allege that BTG acted with scienter. 31 U.S.C. §3729(b)(1). Relator, moreover, concedes that BTG could not have known about the alleged fraud because BTG became a co-owner of the '438 Patent only after it issued

> Subsequent to the issuance of the '438 patent, there was a proceeding to correct inventorship in which Dr. Johann S. de Bono was added as an inventor to the '438 patent. BTG is the owner of Dr. de Bono's inventions and thus asserts co-ownership of the '438 patent along with Janssen.

SAC ¶91.

Second, the SAC lacks any particularized allegations that could establish BTG violated the FCA, 31 U.S.C. §3729(a)(1)(A)-(B)—namely, that BTG:

- Knowingly presented or "cause[d]" to be presented any claims for payment or approval to government reimbursement programs for Zytiga.
- Knowingly made or "cause[d]" the making of any false statements to any government agency (much less any government reimbursement program) relating to the pricing of Zytiga, or claims for Zytiga.

Rule 9(b) requires Relator to "state with particularity the circumstances constituting fraud or mistake," *see Foglia*, 754 F.3d at 155, including "the who, what, when, where and how of the events at issue," *Moore*, 812 F.3d at 307

That Relator makes allegations against "Defendants" collectively, without identifying which Defendant did what, cannot satisfy his pleading burden. As multiple courts of appeals have held, "Rule 9(b) does not allow a complaint to merely lump multiple defendants together but requires plaintiffs to differentiate their allegations when suing more than one defendant and inform each defendant separately of the allegations surrounding his alleged participation in the fraud." *Swartz v. KPMG LLP*, 476 F.3d 756, 764–65 (9th Cir. 2007) (per curiam) (alterations omitted); *see Cornielsen v. Infinium Capital Mgmt., LLC*, 916 F.3d 589, 599 (7th Cir. 2019) ("[A] complaint that attributes misrepresentations to all defendants, lumped together for pleading purposes, generally is insufficient."); *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993) ("Rule 9(b) is not satisfied where the complaint vaguely attributes the alleged fraudulent statements to 'defendants.'"). A relator thus cannot satisfy Rule 9(b) in gross; he must, "at a minimum[,] identify the role of each defendant in the alleged fraudulent scheme." *U.S. ex rel. Lee v. Corinthian Colls.*, 655 F.3d 984, 998 (9th Cir. 2011). That rule makes good sense. Rule 9(b) is designed to give defendants "notice of the claims against them, [to] provide[] an increased measure of protection for their reputations, and [to] reduce[] the number of frivolous suits brought solely to extract settlements." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997). Vague and conclusory allegations that fail to differentiate meaningfully between the actions

allegedly taken by one defendant and those taken by another defeat those purposes. Because, as to BTG, the SAC "vaguely attributes the alleged fraudulent statements "to 'defendants,'" *Mills*, 12 F.3d at 1175, it fails to meet Rule 9(b)'s heightened standard and should be dismissed.

The FCA's proximate-cause standard reinforces the fatal deficiencies of Relator's pleading against BTG. Relator cannot drag BTG into this case by contending only that BTG was involved in an attenuated causal chain of alleged falsity; this falls short of alleging proximate causation arising from BTG's specific, alleged conduct. *See, e.g., United States v. Hibbs*, 568 F.2d 347, 349 (3d Cir. 1977) (holding that "a causal connection must be shown between loss and fraudulent conduct and that a broad 'but for' test is not in compliance with the statute"); *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006) (describing FCA's proximate-cause standard as "winnowing ... claims with only attenuated links between the defendants' specific actions and the presentation of the false claim"), *overruled on other grounds by Cochise Consultancy, Inc. v. U.S. ex rel. Hunt*, 139 S. Ct. 1507 (2019); *United States v. President & Fellows of Harvard Coll.*, 323 F. Supp. 2d 151, 186–87 (D. Mass. 2004) ("To 'cause' the presentation of false claims under the FCA, some degree of participation in the claims process is required."); *U.S. ex rel. Polansky v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 512–14 (E.D. Pa. 2016) (similar). Merely co-owning and enforcing a patent is not enough.

CONCLUSION

All claims against all Defendants should be dismissed for the reasons stated in Parts I through III above. The claims against BTG should be dismissed for the additional and independent reasons set forth in Part IV. And, as this represents Relator's third bite at the apple, the Court should dismiss the SAC with prejudice.

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Respectfully submitted,

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